POLICY AND COMMUNICATIONS BULLETIN THE CLINICAL CENTER

Medical Administrative Series

M93-13 (rev.) 18 July 2000

MANUAL TRANSMITTAL SHEET

SUBJECT: Policy for the Use of Multiple Dose and Single Dose Vials for Injection

- 1. <u>Explanation of Material Transmitted:</u> This issuance transmits the policy of the Clinical Center regarding the use and handling of multiple dose and single dose vials containing materials used for injection. The policy was reviewed by the Medical Executive Committee on 18 July 2000 and approved with changes.
- 2. Material Superseded: MAS No. M93-13 (rev.), dated 17 June 1997
- 3. Filing Instructions: Pharmacy Section

Remove: No. M93-13 (rev.), dated 17 June 1997

Insert: No. M93-13 (rev.), dated 18 July 2000

DISTRIBUTION

Physicians, Dentists and Other Practitioners Participating in Patient Care

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M93-13 (rev.)

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SUBJECT: Policy for the Use of Multiple Dose and Single Dose Vials for Injection

PURPOSE

To identify a standard approach for handling medication vials which minimizes patient risk.

POLICY

Injectable materials contained in single dose or multiple dose vials shall be handled in a manner designed to prevent contamination.

PROCEDURES

Multiple Dose Vials for Injection

• Scope

Multiple dose vials for injection contain sterile parenteral solutions with antimicrobiological preservatives added to the dosage forms to protect them from microbial contamination.

The use of IV minibags or IV bottles as multiple dose vials is prohibited.

Care and Handling

Solutions in multiple dose vials shall be inspected for clarity, turbidity, integrity, and the presence of

particulate matter before each use. Multiple dose vials containing suspensions shall be inspected for integrity and foreign matter. Multiple dose vials suspected of being compromised shall be discarded.

The diaphragm of the vial shall be inspected before entry. If the integrity of the stopper is in any way compromised, the vial shall be discarded. The diaphragm shall be cleansed with a 70% isopropyl alcohol swab before each entry. General principles of aseptic technique shall be maintained.

Unless refrigeration is required for drug stability, as indicated on the label, the vial shall not be stored in the refrigerator.

Multiple dose vials (MDVs) do not require dating when initially entered. Pharmacists conducting nursing unit inspections will discard any MDVs that have been entered. Nursing staff may elect to date MDVs if they don't want the vials discarded because of cost, scarce supply, or frequent use (e.g., insulin or skin tests). An arbitrary 30-day expiration date or the manufacturer's labeling guidelines will be applied to all MDVs that have been entered. MDVs which have been entered and exceed these guidelines will be discarded. Pharmacists will consult with nursing staff before discarding dated items.

Single Dose Vials for Injection

• Scope

Single dose vials for injection contain sterile parenteral solutions without any antimicrobiological preservatives added to the dosage forms ("preservative free"). These solutions are not protected from microbial contamination.

Care and Handling

Single dose vials shall be discarded after each entry. An exception is made for the Pharmacy Department, which uses a laminar flow hood and a controlled environment.

The dating for single dose vials in the Pharmacy Department is 24 hours.

The diaphragm of the vial shall be cleansed with a 70% isopropyl alcohol swab prior to entry. General principles of aseptic technique shall be maintained.